REMARKS

I. Claim Rejections – 35 U.S.C. §103(a)

A. US 6,245,351 to Nara et al. ("Nara") in view of US 5,753,265 to Bergstrand et al. ("Bergstrand")

Claims 1, 3, 6-8, 12-18, 20 and 25-29 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand.

Claim 1 has been amended to clarify that the claimed dosage form comprises a core material and an outer layer covering the core material. The core material is coated with the outer layer which is a semipermeable membrane comprising a single polymer composition containing a water insoluble polymer and a modifying agent. The water insoluble polymer is selected from the group consisting of cellulose ethers, cellulose esters, polyvinyl esters and acrylic polymers. Support for the claim amendments is provided by the specification at page 8, lines 24-25, Examples 3-4 and Figures 1-4.

Specifically, Example 3 is directed to the preparation of the claimed dosage form having an outer layer covering the core material wherein the outer layer is the semipermeable membrane comprising a single polymer composition. Example 4 is directed to the testing of the coated pellets prepared in Example 3 for gastric acid resistance and dissolution. Each of Figures 1-4 illustrate the structure of the claimed dosage form comprising a core material coated with an outer layer which is the semipermeable membrane.

In contrast to the claimed invention, Nara discloses a dosage form having an outer layer comprised of two or three polymers:

- a water insoluble polymer;
- a swellable polymer; and
- an optional hydrophilic substance (See claims 1 and 9).

Furthermore, all of the working Examples 1-11 are directed to a coating composition containing 2-3 polymers:

- ethyl cellulose as the water insoluble polymeric component;
- Carbomer/HIVISWAK as the water soluble, swellable polymer; and
- optionally hydroxypropylmethyl cellulose as the hydrophilic polymer.

Thus, it can be said that Nara teaches away from the claimed invention which is characterized by an outer layer, i.e., the semipermeable membrane, comprising a single polymer composition containing a water insoluble polymer and a modifying agent..

On page 8 of the Office Action, the Examiner states that Nara discloses a coating layer comprising a single polymer such as ethyl cellulose (See col. 6, lines 4-10; and Example 11). However, the support cited by the Examiner is directed to an embodiment wherein the single polymer composition is in the form of an optional separating layer coated on the surface of the core material to separate the drug from the coating composition. As disclosed at column 6, lines 4-10 and Example 11, the separating layer is then overcoated with a coating composition comprising 2-3 polymers as described above. There is no disclosure by Nara that a dosage form having an optional separating layer but not an overcoat of the coating composition is intended for administration. Furthermore, there is no suggestion by Nara that that the optional separating layer contains a modifying agent and is able to disrupt as expressly recited by claim 1.

For all of the foregoing reasons, Applicants submit that Nara fails to suggest the claimed dosage form comprising a core material coated with an outer layer, wherein the outer layer is a semipermeable membrane comprising a single polymer composition containing a water insoluble polymer and a modifying agent, and wherein the semipermeable agent is able to disrupt.

The Examiner relies on the secondary reference to Bergstrand of an enteric-coated tablet core having an optional separating layer that is applied onto the core material before applying the enteric coating layer(s). Bergstrand discloses that the optional separating layer is prepared from pharmaceutically acceptable compounds, such as those disclosed at column 7, lines 57-63, whether used alone or in mixtures. The optional separating layer may include additives such as plasticizers, colorants, pigments, fillers, anti-tacking and antistatic agents (col. 7, lines 63-67).

The Examiner alleges that it would been obvious at the time the claimed invention was made to combine Nara and Bergstrand to arrive at the claimed invention. Applicants respectfully disagree.

Applicants submit that the combination of Nara and Bergstrand fails to suggests the claimed invention since the outer layer disclosed by the primary reference to Nara is comprised of two or three polymers: a water insoluble polymer; a swellable polymer; and an optional hydrophilic substance. In contrast, the claimed dosage form is distinguishable over the cited

combination of references by an outer layer which is the semipermeable membrane comprising a single polymer composition containing a water insoluble polymer and a modifying agent, wherein the semipermeable membrane is able to disrupt and the dosage form is not enteric coated.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established. Accordingly, withdrawal of the §103 rejection of claims 1, 3, 6-8, 12-18, 20 and 25-29 based on the combination of Nara and Bergstrand is requested.

B. Nara, Bergstrand and US 5,225,202 to Hodges et al. ("Hodges")

Claims 30 and 31 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand and Hodges.

The Examiner relies on the disclosure by Hodges of an enteric-coated tablet core containing the active and a buffering agent within the range of from about 1 to about 20% by weight (col. 3, lines 20-26). The Examiner concludes, therefore, that it would have been obvious to use an alkaline additive in an amount taught by Hodges to obtain a stabile acid-labile composition.

Claims 30 and 31 are directly dependent on claim 1. For all of the reasons given in Section I(A), above, there would have been no motivation at the time the claimed invention was made to combine Nara and Bergstrand to arrive at the claimed invention, for example as defined by claim 1. Hodges does not overcome the failure of the combination of Nara and Bergstrand to establish a *prima facie* case of obviousness. Accordingly, withdrawal of the §103 rejection of claims 30 and 31 is requested.

C. Nara, Bergstrand and US 4,795,644 to Zentner ("Zentner") or US 6,013,281 to Lundberg et al. ("Lundberg")

Claims 9 and 10 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand and Zentner or Lundberg.

Zentner is cited by the Examiner for the alleged disclosure of sodium mono- or di-phosphate as a pH modifying agent. Lundberg is cited for the disclosure of arginine as an alkaline reacting compound.

Claims 9 and 10 are directly or indirectly dependent on claim 1. For all of the reasons

given in Section I(A), above, there would have been no motivation at the time the claimed invention was made to combine Nara and Bergstrand to arrive at the claimed invention, for example as defined by claim 1. Neither Zentner nor Lundberg overcomes the failure of the combination of Nara and Bergstrand to establish a *prima facie* case of obviousness. Accordingly, withdrawal of the §103 rejection of claims 9 and 10 is requested.

D. Nara, Bergstrand and WO 98/54171 ("Cotton")

Claims 4, 5 and 23-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Nara in view of Bergstrand and Cotton.

As stated by the Examiner on page 8 of the Office Action, Cotton is cited for the disclosure of the magnesium salt of S-omeprazole as an active ingredient. Applicants submit that Cotton does not over come the deficiencies of Nara and Bergstrand to establish a *prima facie* case of obviousness for the reasons given in Section I(A). Withdrawal of the §103 rejection of claims 4, 5 and 23-26 is requested.

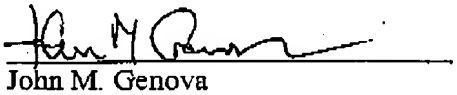
CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1, 3-10, 12-18, 20 and 23-31 are in condition for allowance, which action is earnestly solicited.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: March 7, 2008

Respectfully submitted,



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